K083925

Enter your 510(k) Summary or Statement. *

510(k) Summary

Per 21 CFR §807.92

NOV 26 2008

Date Prepared:	October 16, 2008
Company	Abbott Laboratories
Division	Abbott Diabetes Care Inc.
Street Address	1360 South Loop Road
City, State Zip	Alameda, CA 94502
Telephone No.	510-749-5400
Fax No.	510-864-4791
Contact Person:	Arul Sterlin Tel No. 510-864-4310 Fax No. 510-864-4791 arul.sterlin@abbott.com
Proprietary Name:	ReliOn Ultima Advance Blood Glucose Monitoring System

Common Name:	Blood Glucose Testing System
Classification Name:	Glucose Dehydrogenase, Glucose, Class II (21 CFR§ 862.1345) Product codes: NBW, LFR, Single Analyte Control Solution, Class I (21 CFR§ 862.1660) Product code: JJX
Predicate Device:	Optium Plus Blood Glucose Test Strips and Precision Xtra Plus Blood Glucose Test Strips (K051213)

Description of the Device:

The ReliOn Ultima Advance Blood Glucose Monitoring System is intended for in vitro diagnostic use (i.e., external use only) and for the quantitative measurement of glucose in fresh capillary whole blood. Both the modified device (ReliOn Ultima Advance Blood Glucose Monitoring System) and its predicate device, i.e. Optium Plus Blood Glucose Test Strips and Precision Xtra Plus Blood Glucose Test Strips (K051213) are indicated for home (lay user) or professional use.

The modified ReliOn Ultima Advance Blood Glucose Monitoring System is substantially equivalent in form, firmware, fundamental scientific technology and performance specifications as the predicate system. The ReliOn Ultima Advance system utilizes amperometric biosensor technology to measure current generated on disposable test strips.

No changes to the strip have been made since the last clearance (Optium Plus Blood Glucose Test Strips and Precision Xtra Plus Blood Glucose Test Strips, (K051213)). The test strips manufacturing process is unchanged and all the performance characteristics are unchanged. The test strips are designed to quantitatively measure glucose (sugar) in fresh capillary whole blood from the fingertip, forearm, upper arm, or base of the thumb, by home or professional users. Both the predicate strips (Optium Plus Blood Glucose Test Strips and Precision Xtra Plus Blood Glucose Test Strips (K051213))and the ReliOn Ultima Advance Blood Glucose Test Strips use the reagent glucose dehydrogenase with nicotinamide-adenine dinucleotide (GDH-NAD) as co-factor.

The predicate meter uses lot specific calibration information contained on the calibrator bar. A calibration bar is contained in every box of test strips and is specific to a lot of test strips. The calibration bar contains the lot specific information to allow the meter to convert electrical current into glucose readings via a calibration slope and intercept. The user is instructed to calibrate their meter each time they open and use a new box of test strips.

The ReliOn Ultima Advance meter is programmed with a predetermined calibration slope and intercept and there is no requirement for the user to insert a calibration bar into the meter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Abbott Diabetes Care, Inc.
c/o Mr. Arul Sterlin
Regulatory Affairs Associate
1360 South Loop Road
Alameda, CA 94502

NOV 2 6 2008

Re: k081975
Trade/Device Name: ReliOn Ultima Advance Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: NBW, LFR, JJX
Dated: October 24, 2008
Received: October 27, 2008

Dear Mr. Sterlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K081975

Device Name: ReliOn Ultima Advance Blood Glucose Monitoring System

Indication For Use:

The ReliOn Ultima Advance Blood Glucose Monitoring System is intended for in-vitro diagnostic use in the quantitative measurement of glucose in fresh whole blood for self-testing by lay users (e.g., from the finger, forearm, upper arm or base of thumb), or by health care professionals. It is not intended to be used for testing neonatal blood samples. The ReliOn Ultima Advance system is indicated for home (lay user) or professional use in the management of patients with diabetes.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081975